

PREET BHARARA
 United States Attorney
 By: HEIDI A. WENDEL
 JEANNETTE A. VARGAS
 CHRISTOPHER B. HARWOOD
 Assistant United States Attorneys
 86 Chambers Street, 3rd Fl.
 New York, NY 10007
 Tel.: (212) 637-2636/2678/2728
 Email: Heidi.Wendel@usdoj.gov
 Jeannette.Vargas@usdoj.gov
 Christopher.Harwood@usdoj.gov

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; the States of	:
CALIFORNIA, COLORADO, CONNECTICUT,	:
DELAWARE, FLORIDA, GEORGIA, HAWAII,	:
ILLINOIS, INDIANA, LOUISIANA,	:
MARYLAND, MASSACHUSETTS, MICHIGAN,	:
MINNESOTA, MONTANA, NEVADA,	:
NEW HAMPSHIRE, NEW JERSEY, NEW	:
MEXICO, NEW YORK, NORTH	:
CAROLINA, OKLAHOMA, RHODE	:
ISLAND, TENNESSEE, TEXAS, VIRGINIA,	:
WISCONSIN; the DISTRICT OF COLUMBIA;	:
the CITY OF CHICAGO, and the CITY OF	:
NEW YORK, <i>ex rel.</i> OSWALD BILOTTA,	:
Plaintiffs and Relator,	:
v.	:
NOVARTIS PHARMACEUTICALS	:
CORPORATION,	:
Defendant.	:
-----X	
UNITED STATES OF AMERICA,	:
Plaintiff,	:
v.	:
NOVARTIS PHARMACEUTICALS CORP.,	:
Defendant.	:
-----X	

ECF CASE

Case No. 11 Civ. 0071 (PGG)

**AMENDED COMPLAINT IN
 INTERVENTION OF THE
 UNITED STATES OF AMERICA**

JURY TRIAL DEMANDED

Plaintiff United States of America (the “United States” or the “Government”), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, brings this action against Novartis Pharmaceuticals Corporation (“Novartis”), alleging upon information and belief as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States against Novartis under the False Claims Act, 31 U.S.C. §§ 3729-33 (the “FCA”), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the United States based on Novartis’s violations of the Anti-Kickback Statute (the “AKS”), 42 U.S.C. § 1320a-7b(b), for paying kickbacks to doctors to induce them to prescribe certain Novartis pharmaceutical products that were paid for by federal health care programs. As set forth more fully below, from January 2002 through at least November 2011, Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valtorna and its diabetes drug Starlix, at events that were often little or nothing more than social occasions for the doctors. The payments to the doctors, and the dinners, were kickbacks to the speakers and the attendees to induce them to write prescriptions for Novartis drugs.

2. According to Novartis’s policies, speaker programs are events at which a doctor is paid to educate other doctors and health care professionals regarding the company’s drugs by presenting slides prepared by the company. In practice, Novartis held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drugs at issue. Instead, Novartis simply wined and dined the doctors at high-end restaurants with astronomical costs, as well as in sports bars, on fishing trips, and at other venues not conducive to an educational program. In connection

with these speaker programs, Novartis also paid doctors additional money to attend training events on the drugs, notwithstanding that many of the doctors ultimately spent little or no time discussing the drugs.

3. Novartis's own internal analyses showed that speaker programs had a high return on investment in terms of the additional prescriptions for its drugs written by the doctors who participated in the programs, both as speakers and attendees, with the highest return arising from payments to doctors as "honoraria" for speaking. Indeed, the prescription writing records for numerous doctors reveal that they significantly increased their prescription writing for Novartis drugs after they began receiving honoraria payments in connection with the drugs. For example, one doctor wrote an average of 0.5 prescriptions per month for over three years for the Novartis drug Lotrel before he began receiving honoraria payments. Thereafter, and for the approximately two years that the doctor received honoraria payments in connection with Lotrel, he wrote an average of 59.0 prescriptions per month for the drug.

4. Novartis was well aware that its speaker programs created opportunities to provide kickbacks to doctors. In September 2010, Novartis entered into a settlement with the U.S. Department of Justice to settle FCA lawsuits based in part on false claims arising from illegal remuneration Novartis had paid to doctors through such mechanisms as speaker programs. The company signed a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General agreeing to implement a rigorous compliance program.

5. Yet even after entering into the CIA, Novartis's compliance program was inadequate to prevent illegal payments and other perquisites to doctors in conjunction with Novartis's speaker programs. Novartis did not adequately review its speaker programs to

determine whether the programs were being used for an illegitimate purpose. Furthermore, although many instances of speaker program abuse were reported to Novartis's compliance department, sanctions for illegal conduct were generally mere slaps on the wrist. In some cases, sales representatives who violated Novartis's own speaker program policies were nevertheless promoted. Even after September 2010, Novartis continued to conduct bogus speaker programs that were simply vehicles for paying kickbacks to doctors in the form of honoraria and expensive meals.

6. By paying kickbacks to doctors, Novartis knowingly has caused the submission of thousands of false claims for payment to federal health care programs, including Medicare, Medicaid, TRICARE, and the Veterans Administration health care program. Accordingly, Novartis is liable under the FCA for treble damages and penalties for these claims for payment for Lotrel, Valtorna and Starlix, as well as for other Novartis cardiovascular drugs, as discussed in detail below.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

8. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Novartis does business in this district and some of the false or fraudulent acts occurred in this District.

PARTIES

9. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS"), and its component

agency, the Centers for Medicare and Medicaid Services (“CMS”) (formerly known as the Health Care Financing Administration), which administers the Medicare program and is responsible for overseeing the Medicaid program; the Department of Defense, which administers the TRICARE/CHAMPUS program (TRICARE”); and the Department of Veterans Affairs (“VA”).

10. Relator Oswald Bilotta, a former resident of New York who moved to North Carolina in July 2012, is a former employee of Novartis. In January 2011, Mr. Bilotta filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

11. Defendant Novartis is a subsidiary of Novartis AG, an international pharmaceutical company headquartered in Basel, Switzerland. Novartis, which is headquartered in East Hanover, New Jersey, does business throughout the United States, including in the Southern District of New York.

FACTUAL ALLEGATIONS

I. The Anti-Kickback Statute and the False Claims Act

12. The FCA establishes liability to the United States for an individual who, or entity that, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” § 3729(a)(1)(A); or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” § 3729(a)(1)(B).¹ “Knowingly” is

¹ In May 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”). Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to Novartis’s conduct for the entire time period alleged in the complaint by virtue of Section 4(f) of FERA. Section 3729(a)(1)(A), formerly Section 3729(a)(1) of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009. Section 3729(a)(1) of the pre-FERA FCA provides, in pertinent part, that:

defined to include actual knowledge, reckless disregard and deliberate indifference.

§ 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

13. The AKS makes it illegal for individuals or entities to knowingly and willfully “offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Payments by a pharmaceutical company to doctors to induce them to write prescriptions for the company’s pharmaceutical products that are ultimately paid for by federal health care programs are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

14. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See Social Security*

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- (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .

* * *

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

15. As codified in the Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, *codified at* 42 U.S.C. § 1320a-7b(g), “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].”

16. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify “that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10854.

17. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal health care programs.

18. By providing kickbacks to physicians to induce them to prescribe certain of Novartis’s pharmaceutical products, Novartis has caused false claims to be submitted to federal health care programs.

19. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties are \$5,500 to \$11,000 for violations, such as those alleged here, occurring on or after September 29, 1999.

II. The Federal Health Care Programs

20. For the drugs at issue in this case, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

21. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

22. **Medicare.** Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395, *et seq.* (“Medicare Program”). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, CMS, contracts with private companies (or “Part D sponsors”) to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

23. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary’s Part D sponsor (sometimes through the sponsor’s pharmacy benefit manager, or “PBM”). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of

the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event (“PDE”), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

24. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS’s instructions for the submission of Part D prescription PDE claims data state that “information . . . necessary to carry out this subpart” includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

25. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan’s direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the

difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

26. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

27. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

28. By statute, all contracts between a Part D Plan sponsor and the Department of Health and Human Services must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

29. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the False Claims Act and Anti-Kickback statute. 42 C.F.R. § 423.505(h)(1).

30. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable

provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729, *et seq.*), and the anti-kickback statute (§ 1127B(b) of the Act.”

31. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

32. A Part D Plan sponsor also is required by federal regulation to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled “Certification of data that determine payment,” provides in relevant part:

(1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. . . .

42 C.F.R. § 423.505(k).

33. Compliance with the regulatory requirement that the PDE data submitted to CMS is “true, accurate, and complete” is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

34. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor (“Attestation”). This Attestation states:

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:

The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also

certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

35. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

36. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

37. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the

Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below.” Those requirements include:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

38. **Medicaid.** Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

39. The federal portion of each state’s Medicaid payments, known as the Federal Medical Assistance Percentage (“FMAP”), is based on the state’s per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the “total amount expended . . . as medical assistance under the State plan.” 42 U.S.C. § 1396b(a)(1).

40. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

41. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. For example, the New York regulatory regime provides that an “overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake.” N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c). “Unacceptable practice” is defined to include “[b]ribes and kickbacks,” *id.* § 515.2(b)(5), and lists within this category both “soliciting or receiving,” *id.* § 515.2(b)(5)(ii), and “offering or paying,” *id.* § 515.2(b)(5)(iv), “either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program,” *id.* § 515.2(b)(5)(ii), (iv). New York’s anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366–d –f.

42. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

43. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

44. In New York, for example, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

45. **TRICARE.** TRICARE, (formerly known as CHAMPUS), is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit

program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

46. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

47. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

48. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DoD.CHAMPUS Medical Claim — Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

49. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensings reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

50. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at

least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

51. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

52. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

53. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

54. *Veterans Administration Health Care.* The Department of Veteran Affairs (“VA”) maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

55. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule (“FSS”) program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as 26% less than the manufacturer’s average price based on all sales to commercial customers through a wholesaler or distributor). A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA’s pharmaceutical prime vendor (“PPV”) for distribution of pharmaceuticals. Since May 10, 2004, McKesson Corporation has served as the VA’s PPV. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback from the drug manufacturer for any difference between the contract price paid by the VA and the PPV’s acquisition price.

56. The VA awarded Novartis an FSS contract, Contract No. V797P-5879X (the “Novartis VA contract”), for the procurement of drugs on March 16, 2006. The Novartis VA contract provides: “The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.” The Novartis VA contract further provides: “The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. 327, et seq., Contract Work Hours and Safety Standards Act; 41 U.S.C. 51-58, Anti-Kickback Act of 1986; 41 U.S.C. 265 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. 423 relating to procurement integrity.”

III. Novartis Was Well Aware That Speaker Programs Without Sufficient Controls Could Violate the Anti-Kickback Statute

57. Novartis recognized the need to comply with the AKS in promoting its drugs to health care professionals. Novartis’s Ethics and Compliance (“E&C”) Policies, originally issued in 2003 and reissued in January 2006 and in subsequent years, provide that:

The Federal Anti-kickback Statute makes it illegal to knowingly and willfully provide any “remuneration” in return for:

- (1) referring a person to another person for items or services covered under federal health care programs; or
- (2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.

“Remuneration” is defined very broadly and includes any item of value which is provided with the *intent to induce* the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program – not just Medicare and Medicaid. Note again that many state statutes similarly prohibit such activities.

Under the Anti-kickback Statute, it is illegal to solicit (ask for) or receive kickbacks, as well as to offer to pay a kickback. Any of these actions constitutes a felony and is punishable by a fine up to \$25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity's right to provide products and services to patients whose care is paid for by government programs.

(Emphasis added in 2006 version of the Novartis E&C Policies and in subsequent versions.)

Novartis's E&C Policies also acknowledge that "[j]udicial and administrative interpretations of this law have been very broad" and that "[t]he statute is violated if even one purpose (as opposed to a primary or sole purpose) is to induce the Healthcare Provider to prescribe its product."

Novartis's E&C Policies also note that the "government will infer" that a pharmaceutical company has an intent to induce a healthcare provider to prescribe its product when a payment or other benefit to a provider for a purported service "lacks substance."

58. Novartis's E&C Policies also recognize that "relationships with Healthcare Professionals are intended to benefit patients and to enhance the practice of medicine." The policies state that "[i]nteractions with Healthcare Professionals should be focused on providing information about our products, providing scientific and educational information and supporting medical research and education in venues that are conducive to such discussions." They further note that inviting health care professionals to events such as fishing trips "is inappropriate and is not permitted."

59. This language in Novartis's E&C Policies parallels language in the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals ("the PhRMA Code") issued in 2004 and reissued in 2009. Novartis, along with other major pharmaceutical companies, is a member of PhRMA, a signatory to the Code and has announced its intention to abide by the Code. In addition, Novartis has expressly certified that it

is in compliance with the Code. The PhRMA Code provides that “[i]nteractions” between pharmaceutical company employees and health care professionals “should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.”

60. In addition to setting forth general rules, Novartis’s E&C Policies also contain rules specific to speaker programs. Starting in 2003 and continuing through the present, Novartis’s E&C Policies have provided that speaker programs must be held at venues that are “conducive to an exchange of medical information.” As of 2006, Novartis’s E&C Policies have also provided that “[f]ood and beverages are intended to be ancillary to meaningful discussion,” must be in “modest amounts (quantity and cost),” and must be “incidental to a professional discussion or interaction.” (Emphasis in original.)

61. These policies parallel the PhRMA Code, which states that:

In connection with [speaker programs and other promotional events], it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

In addition, the PhRMA Code provides that “[c]ompanies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.” Further, it provides that “companies should not provide any entertainment or recreational items, such as . . . vacation trips, to any healthcare professional who is not a salaried employee of the company.”

62. In further recognition that speaker programs must have a legitimate purpose to comply with the AKS, at all times relevant to the complaint, since 2003 and continuing through

the present, Novartis's E&C Policies have also required that speakers make a presentation using a slide deck provided to them by Novartis. In addition, Novartis's E&C Policies provide that programs must have at least three health care professionals in attendance and that at least one Novartis sales representative must be present at every speaker program. Since at least 2008, Novartis's E&C Policies have also provided that doctors or other practitioners from the speaker's own practice cannot be included in determining whether a program has at least the minimum three attendees.

IV. In September 2010, Novartis Entered into a Settlement With the Federal Government and the States for Speaker Program Fraud, Among Other Unlawful Activity, and Novartis Became Subject to a Corporate Integrity Agreement

63. On September 27, 2010, Novartis settled FCA claims with the federal government and the states, based in part on AKS violations. The settlement stated that Novartis had "provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel and meals), to health care professionals to induce them to promote and prescribe the drugs Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)."

64. At the same time as the settlement, Novartis also entered into a CIA with the Office of Inspector General of the Department of Health and Human Services. The CIA requires Novartis, among other things, to "ensure that [its] Policies and Procedures address . . . appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the federal anti-kickback statute . . . and the False Claims Act . . ." CIA at Section III(B)(3)(c). The CIA also provides that Novartis's compliance policies and procedures must "address . . . programs to educate sales representatives, including but not limited to presentations by [health care professionals]," and

“be designed to ensure that the programs are used for legitimate and lawful purposes” *Id.* at (3)(l).

65. The CIA also requires that Novartis’s compliance policies “address . . . compensation (including through salaries, bonuses, and contests) for . . . sales representatives” and be “designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Novartis’ Government Reimbursed Products” *Id.* at (3)(q).

V. The Drugs in Novartis’s Cardiovascular Division

66. At all times relevant to the complaint, Novartis sold the drugs Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valtorna, Tekamlo, and Starlix as part of its cardiovascular (“CV”) division.

67. At all times relevant to the complaint, Novartis sold these drugs through a network of sales representatives who called on health care professionals throughout the United States. The drugs in Novartis’s CV division were promoted together by sales representatives in various combinations. For example, a sales representative might be assigned to promote Lotrel and Diovan, or Diovan, Tekturna, and Valtorna to particular doctors.

68. With the exception of Starlix, each of the drugs was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of hypertension. They were approved in the following years:

- Lotrel in 1995
- Diovan in 1997
- Diovan HCT in 1998
- Tekturna in 2007

- Exforge in 2007
- Tekturna HCT in 2009
- Exforge HCT in 2009
- Valturna in 2009
- Tekamlo in 2010

69. Starlix was approved by the FDA in October 2000 for the treatment of diabetes.

70. Many of Novartis's CV drugs are closely related from a clinical perspective. For example, Valturna is a combination of Tekturna and Diovan, while Diovan HCT is a combination of Diovan and a diuretic.

VI. Novartis Created Incentives for Sales Representatives to Use Speaker Programs as Kickbacks Without Sufficient Controls to Prevent Kickbacks from Occurring

71. From 2002 through at least 2011, Novartis conducted speaker programs as a key component of its promotional activities aimed at increasing sales of its drugs. For example, according to Novartis's data, it spent over \$65 million and conducted more than 38,000 speaker programs for Lotrel, Starlix and Valturna during the period from January 1, 2002 through November 2011. Of this \$65 million, Novartis spent nearly \$51 million for approximately 29,000 speaker programs on Lotrel between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Starlix, Novartis spent nearly \$4 million for approximately 3,200 speaker programs between 2002 and 2007, when a generic competitor pharmaceutical product entered the market. For Valturna, Novartis spent approximately \$11 million for more than 6,500 programs from its approval by the FDA in September 2009, until Novartis announced in April 2012 that it would withdraw Valturna from the market in July 2012. Novartis spent millions more to pay its speakers to attend training events on these drugs about which they were also paid to speak.

72. At all times relevant to the complaint, the vast majority of speakers for Novartis's speaker programs were nominated by sales representatives, who picked doctors from among those they called on to promote Novartis drugs.

73. According to Noah Puckowitz, director of Novartis's speaker program bureau from June 2008 through May 1, 2012, Novartis approved all speaker nominations by sales representatives as long as the doctor had a valid license and had not been suspended or debarred from the practice of medicine.

74. A much smaller number of speakers, usually prominent doctors known as "key opinion leaders" ("KOLs"), were chosen by the drug's "brand team," an interdisciplinary group of marketing, sales and scientific specialists who were in charge of the overall management of each brand.

75. Sales representatives were compensated in part based on the number of prescriptions written by doctors on their call lists. This created incentives for sales representatives to use speaker programs as a vehicle to pay kickbacks to doctors to increase their compensation.

76. At all times relevant to the complaint, Novartis sales representatives had a quarterly budget for speaker programs, which they were pressured to spend. The evaluation in 2007 of one sales representative in Long Island by her supervisor, a district manager, stated, for example, "I am disappointed that you did not utilize your entire speaker funds again In 2008, if your territory is not at 100% of speaker fund utilization . . . you will be put on a coaching plan immediately." Another sales representative's evaluation in Long Island in 2007 contained identical language.

77. Novartis used these speaker programs as remuneration to induce health care professionals to prescribe Novartis's drugs.

78. Speakers were paid each time that they spoke. Their compensation for each program, known as an "honorarium," was based on such factors as whether the speaker was certified in a specialty, was on the faculty of a teaching hospital, or had any publications or leadership roles in a medical association. However, although these factors affected the level of the honorarium a speaker was paid for each program, a doctor did not have to have any of these qualifications to be chosen as a speaker for Novartis. Many of Novartis's speakers on Lotrel and Valtorna and other cardiovascular drugs were family practice doctors and internists, not cardiologists who specialized in treating cardiovascular disease. Likewise, many of Novartis's speakers about Starlix were family practice doctors and internists, not nephrologists who specialized in treating diabetes.

79. Speakers were paid an average of between \$750 and \$1,500 for each program depending on the leveling factors, with some speakers earning as much as \$3,000 per program.

80. Some speakers were also paid honoraria for attending training events on the drugs about which they were also paid to speak. Speakers were paid up to \$3,500 for each training event.

81. In addition to choosing the speakers, sales representatives also selected the attendees at speaker programs and were responsible for inviting them to the programs. As in the case of speakers, sales representatives generally chose attendees from the doctors on their call lists.

82. At all times relevant to the complaint, sales representatives selected the speaker, the topic of the program, and the date for the program. Sales representatives also selected the venues for speaker programs.

83. At all times relevant to the complaint, sales representatives scheduled programs for speakers in a speaker program computer database. From 2007 on, Novartis's speaker program database was maintained by a vendor, Advanced Health Media ("AHM"), on Novartis's behalf.

84. At all times relevant to the complaint, Novartis placed no limit on the number of programs a doctor could attend or how often a doctor could attend the same program. There was no system control to prevent a sales representative from repeatedly selecting the same doctors on his call list as attendees at speaker programs on exactly the same topics. Nor was there any system control that prevented a sales representative from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly.

85. Novartis's E&C Policies require that a speaker program "have at least three Healthcare Professionals in attendance," although an event can "continue if, despite a good faith effort" fewer than three doctors attend. Novartis's E&C Policies note that sales representatives "should plan on inviting enough participants to ensure that the minimum requirement is met." Sales representatives were required to cancel a program if fewer than three attendees were confirmed prior to a program occurring.

86. In practice, many programs took place with less than three health care professionals in attendance. Moreover, many programs took place with no one in attendance except members of the speaker's own medical practice.

87. The vast majority of Novartis speaker programs run by the sales force were held in restaurants. At all times relevant to the complaint, Novartis sales representatives were required to choose a restaurant that complied with Novartis's E&C Policies on "modest meals." Starting in 2006, Novartis's policy defined modest meals based on locality, with caps of up to \$100-125 per person in major cities such as New York and Los Angeles and \$80-100 in other U.S. locations. The policy noted that "[m]ost business meals are expected to cost substantially less than th[ose] amounts." In 2010, Novartis changed its policies to make the cap \$125 per person nationwide.

88. In practice these limits could be — and were — avoided through attributing amounts over those caps to what Novartis termed an "unmet minimum," which was the difference between a restaurant's minimum spend for an event and the per person charge for the event. For example, if a restaurant had a minimum charge of \$2,000 for an event, but only four people attended it, a sales representative could attribute \$1,500 of the costs of the program, the amount exceeding the \$125 per capita cost for four people, to the "unmet minimum" for the program. This practice, among others, permitted Novartis to spend lavishly on food and alcohol well beyond the purported "modest meal" caps in its written policies.

89. Novartis does not require that a restaurant have a private room to be an acceptable venue for a speaker program. Nor does Novartis require that the restaurant have a quiet atmosphere.

90. In addition, although Novartis's E&C Policies provide that only "[m]odest meals at a modest restaurant are . . . acceptable" for speaker programs (emphasis added), Novartis does not prohibit holding programs at restaurants that are high-end for the particular community in which they are located.

91. Novartis had few checks on whether sales representatives reported truthfully on who attended speaker programs they hosted. In many cases, Novartis did not even require signatures on attendance sheets at speaker events.

92. In addition, it was the sales representatives who set up and attended the events who were responsible for reviewing the accuracy of the receipts at venues where speaker programs took place.

93. Sales representatives' supervisors were made aware of each speaker program a sales representative hosted, the attendees who were purportedly present, and other details regarding the program. First line supervisors, called District Managers, and second-line supervisors, called Regional Managers, had access to the speaker program database and received reports regarding speaker programs.

94. In addition, Novartis's management was sent data regarding speaker programs. AHM provided Novartis with monthly reports regarding speaker programs. As part of those reports, as further discussed in Section XI below, Novartis management was notified of numerous instances in which speakers were paid for programs that had indicia of fraud.

VII. Many Thousands of Novartis Speaker Programs Lacked Any Legitimate Purpose

95. Novartis's speaker program data shows that from 2002 through at least 2011, doctors around the country spoke repeatedly to the same attendees on exactly the same topics. The doctors in these clusters took turns in the roles of speaker and attendee, with doctors repeatedly attending programs regarding the very same topics they had spoken about. Few or no slides were shown at many of these programs, and at many of the programs, there was little or no discussion of the relevant drugs.

96. At each of these events, Novartis paid the speaker an honorarium between \$500 and \$3,000, and Novartis paid the tab at the locale or restaurant at which the dinner took place. Novartis also paid many of these speakers an additional honorarium — between \$500 and \$3,500 — for attending training events on the drugs about which there was ultimately little or no discussion.

97. **Brooklyn, New York.** For example, an internist in Brooklyn, New York, Dr. S.M.1, was the speaker at the same program on Valtorna, a presentation entitled “Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB,” 10 times from July 2010 to October 2011, with the same three doctors present at nine of the events. Likewise, Dr. S.M.1 and several of the other doctors who attended her Valtorna events also took turns speaking to each other repeatedly on a Lotrel topic, “Aggressive Strategies for Lowering BP in At-Risk Patients,” in 2007. A Novartis sales representative was present at each of these events, and five of the Valtorna events were hosted by the same sales representative.

98. **Bronx, New York.** Similarly, a doctor in the Bronx, New York, Dr. B.A., spoke on the same Valtorna topic, “Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB,” four times from November 2010 to September 2011, with one doctor attending all four times and two doctors attending three times. Dr. B.A. also attended that same program three times between April 2010 and September 2011 with many of the same doctors to whom he also gave that program. At many of the programs involving this cluster of doctors no slide presentation was shown to the attendees. The Novartis sales representatives who were present at these programs told the doctors not to present the slides.

99. Dr. B.A. also spoke on Lotrel. Between Valtorna and Lotrel, Dr. B.A. received \$16,750 in speaker fees.

100. *Tallahassee, Florida.* Likewise, a doctor in Tallahassee, Florida, Dr. C.V.S., was paid \$3,750 for speaking on the same Lotrel topic, “Aggressive Strategies for Lowering BP in At-Risk Patients,” five times in a nine-month period in 2006 and 2007 with the same four doctors repeatedly in attendance. One of these doctors attended four of the events, including two programs that were only one week apart. Another attended three events, including two programs that were only a week apart. At one event, there was only one attendee, a doctor who repeatedly attended the same program.

101. Dr. C.V.S. was also paid \$3,250 for speaking on another Lotrel topic, “Rationale for Combination Therapy in the Treatment of Hypertension” (hereinafter “Rationale for Combination Therapy”), three times in early 2005 with the same two doctors in attendance at all three programs and three other doctors in attendance at two. Despite having spoken on the topic three times in early 2005, Dr. C.V.S. also attended a program in early 2005 given by one of the attendees at Dr. C.V.S.’s programs, on this very same topic. Overall, Novartis’s data shows that the same six doctors attended the same program collectively 23 times in six months.²

102. Specifically, regarding this Lotrel topic and this cluster of doctors:

- On February 1, 2005, Dr. C.V.S. presented “Rationale for Combination Therapy,” and five other doctors attended.
- On February 8, 2005, Dr. C.V.S. attended a presentation of “Rationale for Combination Therapy” by one of the attendees at his programs even though he had presented that program one week earlier, on February 1, 2005, with that doctor as an attendee. Also present at both events were three other doctors who had attended the program on February 1, 2005.
- On March 9, 2005, the same five doctors who attended the February 1 and February 8 programs again attended “Rationale for Combination Therapy,” with Dr. C.V.S. as the speaker.

² The term “collectively” is used in this complaint to indicate the total number of instances of attendance by attendees at an event, not including the speaker.

103. In addition, Dr. C.V.S. was paid to speak on a third Lotrel topic, "Using Combination Therapy and Optimizing Treatment of Hypertension," five times in an 11-month period in 2005 and 2006 with many of those same doctors in attendance at each of the programs.

104. One of the doctors in this cluster was paid between \$50,000 and \$75,000 by Novartis for speaker programs from October 2003 to May 2011.

105. At many of the speaker programs in which these Tallahassee doctors participated, no slides were presented, particularly when, as often occurred, there were only a small number of attendees at the programs. Even when slides were shown at a program, the speaker often would do a truncated version of the slides.

106. At many of the speaker programs involving this cluster, conversation about the drug was a very small part of the event. The doctors mostly talked about other things.

107. **Baltimore, Maryland.** In metropolitan Baltimore, Maryland, the same four doctors attended speaker programs together on the same two Lotrel topics, "Aggressive Strategies for Lowering BP in At-Risk Patients" and "Achieving Blood Pressure Goal in More Patients by Using More Effective Drug Combinations," collectively 27 times on 14 dates during the period from August 2005 through May 2007, with one of the doctors as the speaker at all but one of the events. The speakers gave little or no presentation at these events and often would just give the drug at issue a token mention. The Novartis sales representatives who were present did not object.

108. **Union, New Jersey.** In the Union area in New Jersey, the same three doctors, including Dr. N.D., attended speaker programs on the same Valtorna topic, "Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB," collectively 23 times on eight dates during the period June 2010 through November 2011. In that time frame, Dr. N.D.

purportedly gave all eight presentations. For seven of these eight events the only doctors in attendance were Dr. N.D. and the two other doctors referenced above.

109. In addition, Dr. N.D. and these other two doctors collectively attended speaker programs together on the two Lotrel topics, “New Perspectives on the Use of Combination Therapy in HTN: The Challenge of Getting to Goal” and “Using Combination Therapy and Optimizing Treatment of Hypertension,” and a Starlix topic, “The Importance of Meal Time in Lowering HbA1c,” 22 times on ten dates during the period from October 2004 through August 2007. The speaker for all 10 events was Dr. N.D.

110. These programs typically had an average of only three or four people in attendance and sometimes as few as two people. The programs were usually attended by the same people, even if, as was often the case, they had attended the same program only weeks earlier. Dr. N.D. did not show any slides at the programs at least half the time and sometimes would do an abbreviated slide presentation, skipping some slides and fast forwarding through others. Far from objecting, the vast majority of the time the Novartis sales representatives who were present at the events indicated that they were glad that the program was just a dinner party instead of a genuine speaker program. In addition to being paid \$31,100 for “speaking” at Lotrel, Starlix and Valtorna programs, Dr. N.D. was also paid another \$8,500 for purportedly attending training events on these drugs.

111. *Edgewater, New Jersey.* Another cluster of seven doctors in Edgewater, New Jersey, collectively attended speaker programs on the same Valtorna topic, “Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB,” 33 times on 10 dates during the 10-month period from March 2010 through December 2010, with the doctors taking turns as speaker and attendees. One of these doctors was paid as the speaker on the topic three

times and attended programs on that topic seven times, and another doctor in the cluster was paid to speak on the same topic four times and attended programs on the same topic four times, including two instances in which he spoke on the topic and then attended the event within the following two weeks. These seven doctors collectively attended speaker programs on another Valtorna topic, "Treatment Decisions: A New Choice in Antihypertensive Treatment," 21 times on five dates in the five-month period from November 2009 through March 2010. There were two instances in which one of the doctors spoke on the topic and attended the event within the following week. In addition, two of the doctors referenced above, and two other doctors, collectively attended speaker programs on a Lotrel topic, "Using Combination Therapy and Optimizing Treatment of Hypertension," 10 times on three dates during the four-month period from May 2005 through August 2005.

112. Instead of going through the slides, the doctors would sometimes just talk amongst themselves. Sales representatives were present at these events and did not require the doctors to show the slides.

113. *East Orange, New Jersey.* Another cluster of four doctors in the East Orange area of New Jersey, including Dr. D.S.1, collectively attended speaker programs on the same Valtorna topic, "Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB," nine times on three dates in a five-month period between June 2010 and October 2010. Dr. D.S.1, who was paid as the speaker at these three programs, received in total over \$40,000 from Novartis to speak on Lotrel, Valtorna and Starlix. Dr. D.S.1 also received more than \$6,000 for allegedly attending training events on Lotrel and Valtorna. Another doctor, who works in the same office as Dr. D.S.1, attended 12 of Dr. D.S.1's speaker programs. Moreover, between October 2006 and July 2007, Novartis's speaker program records indicate that Dr. D.S.1

and this other doctor were both paid honoraria, of \$1,500 and \$1,000, respectively, as the speakers at six events at which they purportedly both spoke. Yet Dr. D.S.1 and this other doctor did not both speak at any event.

114. ***Bethlehem, Pennsylvania.*** A cluster of four doctors in Bethlehem, Pennsylvania, attended the same Valtorna event, “Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB,” collectively 27 times on nine dates between May 2010 and June 2011. One of the doctors was paid to speak at eight of the events. Sales representatives were present at each of these speaker programs and were responsible for inviting the same doctors repeatedly to the same events.

115. ***Pittsburgh, Pennsylvania.*** In Pittsburgh, Pennsylvania, the same five doctors, including Dr. B.D., collectively attended speaker programs on the same two Lotrel topics, “Rationale for Combination Therapy,” and “Achieving Healthier BP Goals: Focusing on the Impact of Elevated SBP With Increasing Age,” 14 times on eight dates during the period from October 2004 through November 2005. Dr. B.D. spoke at seven of the eight events. When there were few attendees at the events, which often occurred, the doctors did not give a slide presentation.

116. Another cluster of seven doctors in Pittsburgh, Pennsylvania, also repeatedly spoke at and attended the same programs. These doctors collectively attended Lotrel speaker programs on “Aggressive Strategies for Lowering BP in At-Risk Patients” 14 times on nine dates during the period May 2006 to June 2007. One of the doctors in this cluster, who was the speaker at six of these programs, often would not present the slides because the attendees had already seen them before. As to this cluster of doctors, it was common practice not to go through the slides, especially in restaurants without a private room.

117. **Harrisburg, Pennsylvania.** In Harrisburg, Pennsylvania, a group of five doctors, including Drs. S.G. and D.S.2, collectively attended the same Lotrel program, “Aggressive Strategies for Lowering BP in the At-Risk Patient,” given alternately by all five doctors, 64 times on 16 dates between June 2006 and July 2007. Three of these events occurred within eight days of each other in September 2006, with Dr. S.G. and three of the other doctors attending or speaking at each of the events. Another three of the events occurred within three weeks of each other in March 2007, with Dr. S.G. and two of the other doctors attending all three programs and Dr. D.S.2 and the fifth doctor attending two of them. At many programs no presentation was given and the Novartis sales representatives who hosted the events did not object.

118. **Beckley, West Virginia.** Similarly, a cluster of four doctors in the area of Beckley, West Virginia, including Drs. S.M.2 and R.D., collectively attended the same Lotrel topic, “Using Combination Therapy and Optimizing Treatment of Hypertension,” 15 times on five dates over an eight-month period in 2005 and 2006 with the doctors taking turns as speakers. In addition, that same group of doctors plus two others also took turns speaking to each other repeatedly on several other Lotrel topics in 2006 and 2007. According to Novartis’s data, these six doctors made presentations to each other 24 times on the same Lotrel topics during the period 2005 through 2007.

119. No presentation was given at these events when, as was often the case, only a small number of doctors attended. It was difficult to find doctors who were willing to attend events in the Beckley area and the doctors willing to attend were predominantly only doctors who were also paid speakers.

120. **Rockford, Illinois.** In Rockford, Illinois, a group of ten doctors, including Drs. T.M. and S.D.1, collectively attended the same Valtorna program given by two of the doctors,

“Blood Pressure Efficacy with More Comprehensive RAAS Inhibition Versus an ARB,” 34 times on 12 dates over an 11-month period between April 2010 and March 2011. Dr. T.M. was paid to speak at seven of those programs. Dr. T.M., Dr. S.D.1, and seven other doctors also collectively attended the same Lotrel topic, “Aggressive Strategies for Lowering BP in At-Risk Patients,” 53 times on 18 dates between May 2006 and June 2007. Dr. T.M. purportedly spoke at 15 of those events, and Dr. S.D.1 purportedly spoke at the other three.

VIII. Many Novartis Speaker Programs Were Merely Social Events and Parties at Which Novartis Lavishly Wined and Dined or Otherwise Entertained the Doctors

121. Speaker programs were frequently held at high-end restaurants or in circumstances or at locations that were not conducive to a legitimate educational event.

122. *Fishing trips.* Many speaker programs were held in circumstances in which it would have been virtually impossible for any presentation to be made. Some Novartis speaker programs in Tallahassee, including at least one attended by Dr. C.V.S., were held on fishing trips off the coast, including trips during 2006. Nobody presented any slides on the fishing trips.

123. Novartis also held a speaker program on a Starlix topic on April 25, 2005 at Timber Wolf Lodge, a salmon fishing lodge in Soldotna, Alaska. The speaker was paid an honorarium of \$750.

124. *Hooters.* In addition, Novartis conducted numerous events at various Hooters restaurants. These events were purportedly promotional discussions for doctors at which no one was designated or paid an honorarium as the speaker, called “round table” programs. The events occurred on the following dates in the following locations:

- March 16, 2007 at Hooters in Lexington, KY.
- October 12, 2005 at Hooters in Charleston, WV.
- January 25, 2005 at Hooters in Mobile, AL.

- September 9, 2004 at Hooters in Indianapolis, IN.
- August 25, 2004 at Hooters in Daphne, AL.
- May 30, 2004 at Hooters in Castleton, IN.
- April 27, 2004 at Hooters in Gainesville, FL.

A Novartis sales representative was present at each of these events.

125. *High-End Restaurants and Sports Bars.* In addition, many speaker programs were held at high-end restaurants or sports bars, some of them on Friday or Saturday nights. One of these programs, on the Valtorna topic “Blood Pressure Efficacy With More Comprehensive RAAS Inhibition Versus an ARB” took place on Saturday, June 26, 2010 — just three months before the CIA was signed — at L20, a restaurant in Chicago. Zagat’s describes L20, which received three Michelin Stars that year, as a “swanky dining room inside Lincoln Park’s Belden-Stratford Hotel that delivers an opulent experience . . . ; tabs may bring tears to your eyes, so many say it’s for special occasions only — unless of course you go on someone else’s dime.” On top of the opulent meal, the speaker was paid \$1,500.

126. One of the doctors present at L20 attended speaker programs on that same Valtorna topic five times and another doctor four times. Another doctor who attended programs on that same topic three times, Dr. S.Z., was also paid by Novartis as a speaker on the same topic seven times. One of those programs took place on Saturday, September 18, 2010 — just days before the CIA was signed — at Japonais, a restaurant in Chicago. Zagat’s describes it as a “swanky River North hot spot” with a “hip downstairs bar” and a “dreamy riverside terrace” that “some complain [is] painfully noisy . . . but others who don’t mind bringing big money like the energetic buzz.” In addition to enjoying a lavish meal, the speaker, Dr. S.Z., was paid \$1,500 for this event.

127. Dr. S.Z. was also paid \$1,500 for a program on the same Valtorna topic on Saturday, July 2, 2011 — ten months after the CIA was signed — at Mastro's Steakhouse, another high-end restaurant in Chicago. Zagat's describes it as serving "overflowing martinis and towering seafood appetizers [that] put this decadent and very expensive über-steakhouse near the top of local spots; excellent servers will leave guests pampered and satiated in posh bi-level environs replete with chandeliers and white linens, and live piano music nightly means the bar atmosphere rocks." Moreover, the dinner was attended by only three doctors, all of whom had already attended that same program multiple times.

128. Dr. S.Z. was also paid \$1,500 to give a speaker program on a Lotrel topic on Friday, March 2, 2007, at Billy Barooz, a sports bar in Champaign, Illinois, that advertises itself as having twelve 42-inch flat screen TVs. The bar has no private room.

129. Dr. S.Z. was also paid to speak at his own office eight times. On one of those occasions, October 21, 2004, only one attendee was present for a program on a Lotrel topic, and the total amount spent on the meal was \$1,000, along with a \$1,000 honorarium to Dr. S.Z. On two other occasions there were no attendees present and the doctor was paid a \$500 honorarium for each event. Not only was Dr. S.Z. paid for each of the above speaking programs on Valtorna and Lotrel, but he was also paid thousands more for purportedly attending training events on those drugs.

130. Moreover, many other speaker programs flagrantly violated any concept of a "modest meal" based on the cost. For example, Novartis conducted speaker programs on Lotrel topics for a cluster of doctors in the Washington, D.C. area with the following cost:

- \$2,628 for dinner for seven people (approximately \$375 per person) at The Caucus Room in Washington, D.C. on March 1, 2005. The speaker was paid a \$3,000 honorarium. One of the doctors present attended the same program six times;

another attended the same program five times and spoke twice on the topic; and another attended the same program once and spoke four times on the topic.

- \$2,016 for dinner for three people (approximately \$672 per person), including the speaker, at Smith & Wolensky in Washington, D.C., on July 7, 2005. The speaker was paid a \$1,000 honorarium. One of the two attendees was present at the same program at The Caucus Room a few months earlier.
- \$1,719 for dinner for seven people (approximately \$245 per person) at IndeBleu, described in Zagat's as an "ostentatiously hip" spot for "beautiful people" on March 28, 2006. The speaker was paid a \$1,000 honorarium.
- \$1,145 for dinner for three people (approximately \$381 per person) at Ruth's Chris Steakhouse in Arlington, Virginia, on October 10, 2006. One of the two attendees was present as an attendee at the same program three times and also spoke on the topic.
- \$517 for dinner for two people (approximately \$258 per person) at Oceanaire in Washington, D.C. on March 21, 2007. The speaker was paid an honorarium of \$1,000. The only attendee had attended the program previously.

131. Novartis also conducted a speaker program on a Lotrel topic on October 11, 2006, at Ruth's Chris Steakhouse in Indianapolis, Indiana, for two attendees and a speaker, with a meal cost of \$2,159 (approximately \$719 per person) and a \$1,400 honorarium to the speaker. The same speaker was also paid \$2,000 in total to speak on Lotrel topics at various doctor's offices on August 20, 2003; September 10, 2003; December 5, 2003; and December 18, 2003, even though, according to Novartis's data, there were no attendees at any of these programs.

132. Likewise, Novartis conducted the following additional speaker programs on Lotrel topics with astronomical dinner costs:

- A program on February 18, 2005 for three attendees and a speaker at Sushi Roku in Pasadena, California, with a meal cost of \$1,259 (approximately \$314 per person), and a \$1,000 honorarium for the speaker. Novartis also paid \$500 for a meal for this same speaker, along with a \$1,000 honorarium for a program on April 23, 2004 at AOC Restaurant, a wine bar in Los Angeles, at which there were no attendees reported. This same speaker was also paid \$1,000 and \$750 respectively for programs on March 20, 2003 and September 30, 2003 at which there were no attendees reported;

- A program on December 12, 2005 for two attendees and a speaker at Nobu in Dallas, Texas, with a meal cost of \$9,750 (approximately \$3,250 per person);
- A program on January 18, 2006 for four attendees and a speaker at Swan Lake public garden in Sumter, South Carolina, with a meal cost of \$2,023 (approximately \$404 per person);
- A program on Valentine's Day, February 14, 2006, for two attendees and a speaker at Fleming's Prime Steakhouse and Wine Bar in West Des Moines, Iowa, with a meal cost of \$3,127 (approximately \$1,042 per person); and
- A program on March 16, 2006 for three attendees and a speaker at Mahogany, a high-end steakhouse in Oklahoma City, Oklahoma, with a meal cost of \$1,452 (approximately \$363 per person).

133. Many speaker programs were not conducted in private rooms, either because the restaurant did not have one or because Novartis chose not to conduct the program in a private room. For example, Dr. B.A., the primary speaker in the Bronx, New York, cluster discussed above, was paid \$500 to speak at Nobu, a famously high-end restaurant in New York City in May 2006 at a dinner attended only by himself, two of his doctor friends, one of whom brought his girlfriend (who was not a health care professional) and a Novartis sales representative. The dinner did not occur in a private room and no slides were presented.

134. In fact, many Novartis speaker programs did not take place in a private room, making it difficult or impossible to hear the speaker or to show slides. When speaker programs occurred in the public space of a restaurant it was common practice not to show the slides.

135. Many Novartis speaker programs were merely social events for the doctors and Novartis sales representatives, who were often friends with each other.

136. Aside from not presenting the slide decks, many of the doctors who participated in Novartis speaker programs did nothing but socialize with their friends at the events. Often the only people who would come to a doctor's programs were people who knew the doctor. Novartis sales representatives understood the situation and would frequently ask speakers whom

they should invite. The doctors who were willing to attend programs were often friends with each other who socialized outside the context of speaker programs as well.

137. The conversation at these dinners was generally not about the drug that was the subject of the speaker program. Doctors attended the programs to have dinner together, often at high-end restaurants, and to network with colleagues. They also attended each other's programs to ensure that they would all continue to be paid as Novartis speakers. The doctors knew that if they did not attend each other's events, the programs could not take place and none of them would continue to get paid by Novartis.

IX. Novartis Made Payments to Doctors for Speaker Programs That Did Not Occur or Were Not Attended by the Medical Personnel Novartis Claimed Were Present

138. In addition, some of the programs for which speakers were paid by Novartis either did not occur at all or did not have the attendees Novartis claims were present. Novartis created phony records for many of these speaker programs to make it appear that they were legitimate, educational programs with an appropriate number of attendees when they were not.

139. For example, Dr. S.M.1, the primary speaker in the Brooklyn, New York, cluster, was seeing patients at her office during the times when Novartis claimed that she was purportedly speaking about Lotrel on March 20, 2007 and April 17, 2007. She was paid an honorarium of \$1,000 for "speaking" on each of those occasions, as well as "ground transportation" expenses, even though she was purportedly speaking at her own office. The purported attendees on these occasions were the exact same attendees that purportedly attended all of her events and whose events she in turn purportedly attended.

140. Novartis also paid honoraria to doctors in West Virginia for speaker programs that did not occur. One of the doctors in the West Virginia cluster was paid for speaking at dinners that he never attended and restaurants that he had never even heard of. According to Novartis's

data, this doctor was paid \$750 to speak at David's at the Club, a high-end restaurant in Bluefield, West Virginia, on October 6, 2005 to three other doctors in the cluster, including Drs. S.M.2 and R.D., on the Lotrel topic "Achieving BP Goal in More Patients by Using More Effective Drug Combinations." According to Novartis's data, this doctor also attended several speaker programs at David's at the Club, including a Lotrel program on September 29, 2005 for which Novartis paid \$750 to Dr. D.R. as the speaker, and a Lotrel program on August 25, 2005 for which Novartis paid \$750 to Dr. S.M.2 as the speaker. Shortly before the September 29, 2005 and August 25, 2005 programs, Dr. R.D. and Dr. S.M.2 were each paid \$1,000 for purportedly attending a Lotrel training event on June 4, 2005.

141. Similarly, Novartis paid honoraria to doctors in Cedar Knolls, New Jersey, for purported speaker programs that did not occur, or were not attended by the medical personnel whom Novartis claims were present. Novartis's data indicates that a nurse attended the following speaker programs on Lotrel topics given by one of the doctors in the cluster when she did not attend the programs:

- February 12, 2007 at Sushi Lounge, a restaurant in Morristown, New Jersey;
- May 2, 2007 at 3 West, a restaurant in Basking Ridge, New Jersey; and
- July 9, 2007 at Basilico, a restaurant in Millburn, New Jersey.

142. Likewise, a doctor in the Cedar Knolls cluster also did not attend many of the events that Novartis's records indicate he attended. He attended only one program given by the primary speaker in the Cedar Knolls cluster, but Novartis's speaker program data indicates he attended 14 speaker programs given by that speaker on the following dates:

- February 27, 2006 at Tre Vigne in Bernardsville, New Jersey;
- March 27, 2006 at Cinque Figlie in Whippany, New Jersey;

- April 4, 2006, May 2, 2006, July 21, 2006, October 9, 2006, and May 14, 2007 at the speaker's office in Cedar Knolls, New Jersey;
- August 24, 2006 at Copeland Restaurant in Morristown, New Jersey;
- November 15, 2006 at Grand Café in Morristown, New Jersey;
- February 12, 2007 at Sushi Lounge in Morristown, New Jersey, a restaurant the doctor had never been to;
- May 2, 2007 at 3 West in Basking Ridge, New Jersey, another restaurant the doctor had never been to;
- May 8, 2007 at Medical Institute in Saddle River, New Jersey;
- June 6, 2007 at Serenade in Chatham, New Jersey; and
- July 9, 2007 at Basilico in Millburn, New Jersey.

At the programs in 2007 on February 12, May 2, June 6, and July 9, Novartis's records indicate that this doctor was one of only three attendees, including the nurse referred to in paragraph 141 above.

143. The same doctor also did not attend the following events that Novartis's records claim he attended at which another doctor was the purported speaker:

- April 19, 2004 and May 8, 2007 at The Medical Institute in Cedar Knolls, New Jersey;
- October 6, 2004 at Cheeseblock in Cedar Knolls, New Jersey;
- August 31, 2005 at an unspecified office in Cedar Knolls, New Jersey;
- April 25, 2005 and November 8, 2005 at a doctor's office at 11 Saddle Road in Cedar Knolls, New Jersey;
- April 11, 2006 at an unspecified location in Cedar Knolls, New Jersey; and
- September 28, 2006 at his office in Cedar Knolls, New Jersey.

144. Novartis also paid a doctor in another cluster in the Toms River area in New Jersey an honorarium of \$1,500 for a speaker program that apparently did not occur. According

to Novartis's data, the program was on Friday, August 4, 2006, in Toms River, New Jersey, at a location reported as "TBD," with a meal cost of \$1 and was purportedly attended by three doctors, two of whom purportedly attended the same program multiple times. Based on Novartis's own data, it appears that this event did not occur, yet an honorarium was paid for it.

X. Novartis Paid Doctors Honoraria and Wined and Dined Them to Induce the Doctors to Write Prescriptions for Novartis Drugs

145. As Novartis found every year starting in 2004, speaker programs had a good return on investment. Novartis's Business Analysis Unit in 2004 reported that "[s]peaker programs for most brands exceed or approach break even after only 5 months and results are expected to improve through [the] year." The "best returns" were on doctors who wrote the highest numbers of prescriptions for Novartis drugs before participating in Novartis's speaker programs, known as "Tier 1" doctors, but "good returns are also possible for the lowest tier," according to Novartis's Business Analysis Unit, which was responsible for measuring the return on investment for speaker programs, among other promotional events.

146. As Paul Rabideau, Novartis's Senior Director of Marketing and Sales Analytics put it, no matter what "tier" a doctor was in he or she could be influenced, and "Tier 1" doctors start off with a higher prescription base so they are more profitable.

147. Novartis intended that the more incentives doctors received in the form of meals, entertainment, and honoraria, the more the doctors would write prescriptions for Novartis drugs. In a "Meeting and Events Analysis" dated November 9, 2004, Novartis's Business Analysis Team noted that "Offering an honorarium is the top factor across all classes" of drugs driving the return on investment with respect to promotional programs. The Business Analysis Unit concluded in 2004 that if a doctor would not attend a "round table" program, which was cheaper

for Novartis because no one had to be paid an honorarium, then “invite [the doctor] to the most expensive speaker program.”

148. In May 2006, Novartis found that speaker programs in 2005 for Lotrel had a return on investment of more than 1.39, meaning that for every dollar spent on the programs, Novartis made more than \$1.39 in revenue on the increase in prescriptions written by these doctors as compared to a control group of doctors who did not participate in speaker programs. For the highest prescribers, the Tier 1 doctors, the return on investment was 2.52, meaning that these doctors wrote an additional \$2.52 in prescriptions for Lotrel for every dollar Novartis spent on the programs in which they participated. For Tier 2 doctors, the return on investment was even higher — 2.77 — while for Tier 3 doctors, it was 1.57. Moreover, according to Mr. Rabideau, the return on investment from speaker programs increased over time up to 18 months after each speaker program.

149. Novartis used its speaker programs to drive prescriptions and doctors knew it. Sales representatives chose doctors to be speakers based on high levels of prescriptions, which the doctors had to maintain or increase in order to continue to be invited to present programs.

150. Moreover, individual doctors’ writing of prescriptions for Novartis drugs closely tracks the dates on which the doctors received honoraria in connection with the drugs. Many doctors significantly increased their prescription writing for Novartis drugs once they began receiving honoraria in connection with the drugs. Other doctors increased their prescription writing only after they started receiving consistent honoraria payments. Many doctors, moreover, continued to increase their prescription writing as they received additional honoraria payments.

151. For example, according to Novartis's speaker program data, Dr. S.D.2, a doctor from Baltimore, Maryland, substantially increased the number of Lotrel prescriptions that he wrote after he began receiving honoraria from Novartis in connection with the drug. Before Dr. S.D.2 began receiving honoraria, from January 2002 through May 2005, he wrote an average of only 0.5 prescriptions of Lotrel per month. Thereafter, from June 2005 through July 2007 — the period during which Dr. S.D.2 received honoraria in connection with Lotrel — he received \$30,200 in honoraria payments (\$22,200 for conducting 25 speaker programs and \$8,000 for attending five training events), and his average number of prescriptions per month increased to 59.0. Moreover, during that period, the level of Dr. S.D.2's prescription writing increased as he received more honoraria payments. During the nine-month period from November 2006 through July 2007, Dr. S.D.2 received the bulk of his honoraria payments — \$22,450 (\$18,450 for conducting 20 speaker programs and \$4,000 for attending two training events) — and he wrote an average of 84.8 prescriptions per month.

152. With respect to Valtorna, Dr. S.D.2's prescription writing also increased as he received higher amounts of honoraria. During the five-month period from October 2009 through February 2010, Dr. S.D.2 received his first honoraria payments in connection with Valtorna (\$6,000 for conducting four speaker programs and \$1,250 for attending one training event), and he wrote an average of 12.3 prescriptions per month. During each of the next two five-month periods, from March 2010 through July 2010 and August 2010 through December 2010, Dr. S.D.2 received significantly more honoraria. During each of those periods, he received \$12,000 for conducting eight speaker programs, and his average number of prescriptions per month nearly tripled to 36.0 and 33.8, respectively. Over the next 11 months, however, from January 2011 through November 2011, Dr. S.D.2 received only \$10,500 in honoraria payments — less

than half of what he had received during the prior 10-month period — and his prescription writing for Valtorna dropped to an average of 24.3 per month.

153. The prescription writing of Dr. B.D., a doctor in one of the Pittsburgh, Pennsylvania, clusters, reflects a similar trend. Dr. B.D. received honoraria in connection with Lotrel beginning in May 2003 and continuing through June 2007. During that period, the number of prescriptions that he wrote for Lotrel increased greatly, with the highest levels of prescriptions corresponding to the periods in which he received the largest payments from Novartis, namely, September 2004 through June 2005 and February 2006 through June 2007. Before Dr. B.D. began receiving honoraria in connection with Lotrel, from January 2002 through April 2003, he wrote an average of 19.4 prescriptions for Lotrel per month. Thereafter, from May 2003 through June 2007 — the period during which Dr. B.D. received honoraria — he was paid \$14,600 (\$12,100 for conducting 18 speaker programs and \$2,500 for attending two training events), and he wrote an average of 34.3 prescriptions per month. Moreover, during the two shorter periods referenced above when Dr. B.D. received the largest payments from Novartis, September 2004 through June 2005 (\$5,350 for conducting eight speaker programs and attending one training event) and February 2006 through June 2007 (\$8,350 for conducting seven speaker programs and attending one training event), his average number of prescriptions per month increased to 40.1 and 35.5, respectively.

154. Similarly, Dr. B.A., a doctor in the Bronx, New York, cluster, substantially increased the number of Lotrel prescriptions that he wrote after he began receiving consistent honoraria payments from Novartis starting in March 2006. From January 2002 through February 2006, Dr. B.A. received one honoraria payment in connection with Lotrel (\$550 for conducting one speaker program in November 2004), and he wrote an average of only 17.3 prescriptions per

month. By contrast, from March 2006 through April 2007 — the period during which Dr. B.A. received additional honoraria payments in connection with Lotrel — he was paid \$6,200 for conducting seven speaker programs, and his prescription writing for Lotrel skyrocketed to an average of 51.5 per month.

155. Dr. L.M., a doctor from Muscle Shoals, Alabama, also greatly increased the number of Lotrel prescriptions that he wrote after he began receiving consistent honoraria payments from Novartis starting in June 2006. From January 2002 through May 2006, Dr. L.M. received one honoraria payment (\$1,000 for attending one training event in June 2005), and he wrote an average of only 17.6 prescriptions per month. Thereafter, from June 2006 through June 2007 — the period during which Dr. L.M. received additional honoraria payments in connection with Lotrel — he was paid \$17,300 for conducting 16 speaker programs, and his prescription writing more than doubled to an average of 42.3 per month.

156. Dr. L.M.'s prescription writing for Valtorna also increased as he received more honoraria payments in connection with the drug. From October 2009 through January 2010, Dr. L.M. received one honoraria payment in connection with Valtorna (\$1,250 for attending one training event in October 2009), and he prescribed an average of 1.5 prescriptions per month. During the next five months, from February 2010 through June 2010, he received two honoraria payments (totaling \$2,000 for conducting two speaker programs), and his prescription writing increased to an average of 3.5 per month. Thereafter, during the five-month period from July 2010 through November 2010 — the final period during which Dr. L.M. received honoraria payments in connection with Valtorna — his honoraria payments more than doubled (he received a total of \$5,000 for conducting five speaker programs), and his prescription writing similarly increased to an average of 9.2 prescriptions per month.

157. Numerous other doctors also increased the number of prescriptions that they wrote for Novartis drugs after they began receiving honoraria payments from Novartis in connection with the drugs, or increased levels of honoraria payments. For example:

- **Dr. S.M.2 (Beckley, West Virginia, Cluster).** Before Dr. S.M.2 began receiving honoraria in connection with Lotrel in June 2005, his prescription writing for Lotrel had been declining. From January 2002 through December 2003, he wrote an average of 13.2 prescriptions per month, but from January 2004 through May 2005, he wrote an average of only 11.5 prescriptions per month. Thereafter, from June 2005 through July 2007 — the period during which Dr. S.M.2 received honoraria in connection with Lotrel (\$6,500 for conducting seven speaker programs and \$2,500 for attending two training events) — his prescription writing increased to an average of 17.6 prescriptions per month.
- **Dr. R.D. (Beckley, West Virginia, Cluster).** Like Dr. S.M.2, before Dr. R.D. began receiving honoraria in connection with Lotrel in June 2005, his prescription writing for Lotrel had been declining. From January 2002 through December 2003, he wrote an average of 19.5 prescriptions per month, but from January 2004 through May 2005, he wrote an average of only 14.4 prescriptions per month. Thereafter, from June 2005 through May 2007 — the period during which Dr. R.D. received honoraria in connection with Lotrel (\$7,000 for conducting seven speaker programs and \$4,000 for attending three training events) — his prescription writing increased to an average of 24.7 prescriptions per month. Moreover, during the period February 2006 through May 2007, Dr. R.D. received the majority of his honoraria payments — \$8,500 (\$5,500 for conducting five speaker programs and \$3,000 for attending two training events) — and his prescription writing reached its highest levels: an average of 29.6 prescriptions per month.
- **Dr. D.S.2 (Harrisburg, Pennsylvania, Cluster).** Dr. D.S.2 increased the number of Lotrel prescriptions that he wrote after he began receiving consistent honoraria payments in connection with the drug starting in February 2006. From January 2002 through January 2006, Dr. D.S.2 received one honoraria payment (\$1,000 for attending one training event in June 2005), and he wrote an average of only 8.2 prescriptions for Lotrel per month. Thereafter, from February 2006 through June 2006, Dr. D.S.2 received honoraria payments of at least \$1,000 in four of those five months, and he continued to receive honoraria payments through June 2007. During that full period, from February 2006 through June 2007, Dr. D.S.2 was paid \$8,750 (\$7,250 for conducting eight speaker programs and \$1,500 for attending one training event), and his prescription writing doubled to an average of 16.5 per month.
- **Dr. S.Z. (Champaign, Illinois).** Before Dr. S.Z. began receiving honoraria in connection with Lotrel — from January 2002 through May 2003 — he wrote an average of 18.4 prescriptions for Lotrel per month. Thereafter, from June 2003 through May 2007 — the period during which Dr. S.Z. received honoraria in

connection with Lotrel — he was paid \$38,500 (\$32,000 for conducting 29 speaker programs and \$6,500 for attending four training events), and his prescription writing for Lotrel substantially increased to an average of 48.8 per month. Moreover, during the 12-month period when Dr. S.Z. received the most honoraria payments, June 2006 through May 2007 (\$21,000), he wrote his highest levels of prescriptions: an average of 65.3 per month.

- **Dr. S.M.1 (Brooklyn, New York, Cluster).** Dr. S.M.1 did not start prescribing Valtorna until she began receiving consistent honoraria payments in connection with the drug, and thereafter her prescription writing increased as she received more honoraria. Dr. S.M.1 received her first honoraria payment for Valtorna in October 2009 (\$1,250 for attending one training event), but she did not write any prescriptions for Valtorna until February 2010 when she received her second honoraria payment (\$1,500 for conducting one speaker program). From February 2010 through June 2010, Dr. S.M.1 received only that one payment in February 2010, and she wrote an average of only 2.0 prescriptions per month. Dr. S.M.1 received a third honoraria payment in July 2010 (\$1,500 for conducting another speaker program), and she wrote 4.9 prescriptions that month and 16.9 the next month. Thereafter, from September 2010 through October 2011, Dr. S.M.1 received honoraria payments of at least \$1,500 in eight of those 14 months (a total of \$13,500 for conducting nine speaker programs). Over that period, Dr. S.M.1's prescription writing remained at an elevated level: she wrote an average of 14.8 prescriptions per month.
- **Dr. N.D. (Union, New Jersey, Cluster).** Before Dr. N.D. began receiving honoraria in connection with Starlix, from January 2002 through January 2004, he wrote an average of 24.8 prescriptions for Starlix per month. Thereafter, from February 2004 through August 2006 — the period during which Dr. N.D. received honoraria in connection with Starlix — he was paid \$7,500 (for conducting nine speaker programs and attending one training event), and he wrote an average of 32.3 prescriptions per month. Moreover, after Dr. N.D. stopped receiving honoraria in connection with Starlix, he continued to write prescriptions for the drug through December 2007, but he regressed to his pre-honoraria level of prescription writing — from September 2006 through December 2007, he wrote an average of only 24.9 prescriptions per month.
- **Dr. T.M. (Rockford, Illinois, Cluster).** Before Dr. T.M. began receiving honoraria in connection with Lotrel — from January 2002 through January 2003 — he wrote an average of 9.0 prescriptions per month. Thereafter, from February 2003 through June 2007 — the period during which Dr. T.M. received honoraria in connection with Lotrel — he was paid \$30,500 (\$25,500 for conducting 31 speaker programs and \$5,000 for attending three training events), and his average number of prescriptions per month tripled to 27.7. Moreover, the level of Dr. T.M.'s prescription writing increased as he received more honoraria. From February 2003 through December 2004, Dr. T.M. received \$2,800 in honoraria payments, and he wrote an average of 20.4 prescriptions per month. From January 2005 through December 2005, his honoraria payments increased to \$4,100, and his average number of prescriptions per

month increased to 28.1. From January 2006 through December 2006, his honoraria payments again increased to \$10,040, and his average number of prescriptions per month similarly increased to 39.9. During the final six months that Dr. T.M. received honoraria payments, from January 2007 through June 2007, both his honoraria received and his prescription writing remained at an elevated level: \$13,200 and an average of 30.6 prescriptions per month, respectively.

- **Dr. S.D.1 (Rockford, Illinois, Cluster).** Dr. S.D.1 received honoraria payments in connection with Lotrel over the course of 11 months — from July 2006 through May 2007 (\$4,000 for conducting four speaker programs and \$3,000 for attending two training events). During the 11 months before Dr. S.D.1 received honoraria payments, he wrote an average of 14.8 prescriptions for Lotrel per month, whereas during the 11 months that he received honoraria payments, he wrote an average of 27.0 prescriptions per month.
- **Dr. D.S.1 (East Orange, New Jersey, Cluster).** Dr. D.S.1 received \$29,600 in honoraria payments in connection with Lotrel from June 2005 through July 2007, but he received the majority of those payments (\$27,100) during the 13-month period from July 2006 through July 2007. During that period, Dr. D.S.1 received honoraria payments in eight of the 13 months and wrote an average of 52.8 prescriptions per month. During the prior 13-month period, he received honoraria payments in only two months and wrote an average of 44.5 prescriptions per month.

158. As the above examples demonstrate, doctors who received honoraria payments in connection with specific Novartis drugs wrote higher levels of prescriptions for those drugs. Moreover, and more generally, the fact that doctors received honoraria in connection with Novartis's speaker programs increased the likelihood that they would write prescriptions for Novartis drugs. For example, Dr. N.D. was more inclined to prescribe Diovan over comparable drugs in part because of his status as a speaker on Lotrel. Likewise, Dr. S.G.'s (Harrisburg, Pennsylvania, cluster) participation in Novartis's speaker programs influenced his prescription writing. Similarly, the fact that Dr. C.V.S. (Tallahassee, Florida, cluster) was paid as a speaker for a pharmaceutical company increased the likelihood that he would prescribe that company's drugs.

159. In addition to the incentives that the speaker programs provided to doctors, Novartis sales representatives had strong incentives to use speaker programs to reward doctors

for writing prescriptions or to induce them to increase their number of prescriptions, because sales representatives were compensated in part based on how many prescriptions those doctors wrote. The pressure Novartis placed on sales representatives to increase sales was evident to the doctors.

XI. Novartis's Compliance Program Was Inadequate to Prevent Fraud with Respect to Its Speaker Programs

160. Even after Novartis entered into a CIA with the Office of Inspector General of the Department of Health and Human Services in September 2010, its compliance program included insufficient controls to prevent speaker programs from being used as a vehicle for kickbacks to doctors through the payment of honoraria or lavish dinners and entertainment. Novartis had no controls to prevent sales representatives from hosting programs in which the same doctors spoke repeatedly to the same attendees on exactly the same topic.

161. Nor did Novartis have sufficient controls to ensure that speaker programs were occurring as claimed by the sales representatives and recorded in Novartis's speaker program platform. Sales representatives recorded data regarding the attendees at each program in that platform. Considering that sales representatives could benefit financially by paying kickbacks to doctors on their call list, this system for ensuring that programs occurred as documented created incentives for abuse. Novartis often did not even require purported attendees at speaker events to sign the attendance sheets at the programs.

162. Speaker program data was available to and, according to Noah Puckowitz (director of Novartis's speaker program bureau from 2008 to 2012), was sent by sales representatives up the supervisory chain of authority in Novartis's sales force.

163. Novartis management was made aware of the inadequacies in its existing compliance programs and the numerous violations of it that occurred.

164. In fact, Novartis's board of directors was informed of significant compliance issues on March 19, 2009 at a presentation entitled "Representatives [sic] Interactions With Healthcare Professionals," given by the Executive Director of Ethics and Compliance and the Director of Regulatory Compliance. The presentation included the following findings regarding speaker programs:

- "Discrepancies existed between attendees physically present, attendees per Sign In Sheets and attendees per Event Alliance records;"
- "Frequent utilization of venues not conducive to a private business meeting;"
- "An insufficient number of HCPs (<3) in attendance at programs;"
- "Excessive meal and alcohol costs at Field Managed Promotional Speaker Events . . . primarily due to a lack of responsibility for reviewing itemized meal receipts;"
- "Lack of responsibility to monitor the speaker's performance in presenting the approved materials;" and
- "Inappropriate speaker conduct and non-compliance with policies."

165. Despite being aware of these issues, Novartis's response remained inadequate.

166. Moreover, Novartis knew or should have known that its speaker programs continued to be plagued with problems as a result of the monitoring it was required to conduct pursuant to the CIA. Novartis's E&C department, which is responsible for conducting internal audits and investigations of violations of Novartis policies, among other things, monitored only 107 out of thousands of speaker programs in 2011. In each case, Novartis gave notice to the sales representatives hosting the program that a monitor would be attending. Even with a monitor present, the E&C department found that in 44 of the 107 programs monitored — over 40% — there were violations of the "modest meal" policy. In eight out of the 107 programs monitored, despite the presence of the monitor, the "[s]peakers did not present the entire slide deck (skipped some slides)." Moreover, "the host representatives did not ensure the required

slides were presented.” In addition, at 35 of the programs — approximately 33% — the monitor found “inconsistencies with supporting documentation, the most common being the names and number of attendees on the sign in sheet not matching the names and number of attendees recorded in the Event Alliance system.”

167. The director of the E&C department, concluded that, based on these and other violations of Novartis’s policies, sales representatives “didn’t understand their roles” in ensuring that speaker programs were compliant. However, Novartis’s primary response to the problem was to hold a webinar training of sales representatives in January 2012. Novartis did not increase its monitoring of speaker programs, schedule unannounced visits to programs, or interview any doctors who had purportedly participated in speaker programs in response to the problem.

168. A report from the E&C department to Novartis’s Board of Directors on March 9, 2011, indicated that out of 22 speaker programs the E&C department had monitored in the fourth quarter of 2010, the speaker did not present slides at three programs and at eight programs the monitor observed violations of the meal policy. Again, these violations occurred even though the monitor informed the sales representative hosting the program ahead of time that it would be audited.

169. Moreover, when Novartis made findings of speaker program fraud, it imposed sanctions that were mere slaps on the wrist. For example, according to data compiled by the E&C department, an anonymous call was placed to Novartis’s Compliance Alertline in 2009 alleging that a sales representative “was paying off doctors to achieve higher sales numbers.” The E&C department found that “[a]fter an extensive review of [the representative’s] expenses as well as speaker programs, it was revealed that [the representative] paid for [a particular

doctor, Dr. #1] to speak eight (8) times in 2008. The same attendees were present for each program.” Novartis’s investigator also found that the sales representative had “utilized another doctor [Dr. #2] . . . who only spoke twice, but also had the same six attendees present for both programs, including [Dr. #1]. [Dr. #2] was present for six (6) days of [Dr. #1's] programs in 2008.” However, Novartis’s E&C department apparently did not view these problems with repeat attendees as worthy of any response. The only disciplinary action the department recommended for the sales representative was “verbal coaching” regarding “control over alcohol expenses,” based on the large amount of alcohol (such as five bottles of wine for five attendees) that were purportedly purchased at many of the events.

170. Similarly, the E&C department made findings of other conduct indicative of kickbacks. In one instance, Novartis’s E&C department became aware that a sales representative had hosted a speaker program in Montego Bay, Jamaica, in 2008 that cost \$15,000 and was attended by only two Novartis employees and one health care professional. The sales representative who hosted the program was not terminated. The only punishment the sales representative received was reportedly a “conduct memo.”

171. Likewise, according to Novartis’s data, the E&C department made findings in April 2011, after the CIA was signed, that in 2009 a sales representative sponsored a promotional lunch for \$467 at a sports bar called 11/12 Lounge & Sports Bar that was “more of a bar/karaoke night club” than a restaurant, and that was attended only by doctors or other HCPs with neither the sales representative nor any other “NPC [Novartis] sales associate present to hold a medically relevant discussion.” The only discipline the sales representative received was a “conduct memo.”

XII. In Addition to Lotrel, Valtorna and Starlix, Novartis Conducted Fraudulent Speaker Programs With Respect to Other Drugs

172. As discussed in Section V above, in addition to Lotrel, Valtorna, and Starlix, during the period from January 2002 through at least November 2011, Novartis also promoted Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT as part of its cardiovascular division. Although, as relevant to this complaint, the September 2010 settlement released claims related to speaker program fraud for the drugs Diovan, Tekturna, and Exforge through December 31, 2009, the settlement, by its terms, did not release claims for Tekamlo or for any of the HCT forms of these drugs. Numerous speaker programs occurred with respect to Tekamlo and the HCT forms of Diovan, Tekturna and Exforge throughout the time period relevant to this complaint.

173. Moreover, Novartis continued to conduct speaker programs on Diovan, Tekturna, and Exforge after December 31, 2009, through at least the end of 2011. In August, 2010 a doctor reported to Impact Rx, a Novartis vendor specializing in healthcare marketing, that a Novartis “rep stopped by to invite me to a [Diovan] dinner meeting tomorrow night.” In December, 2011 another doctor, discussing a Novartis representative’s promotion of Diovan HCT, reported that the representative “invited me to attend a speaker program.” Likewise, another doctor reported that a “[r]epresentative came by dropping off [Tekturna] samples, and invited me to dinner with my spouse.”

174. Furthermore, the fact that doctors were paid in connection with Novartis’s speaker programs influenced their prescription writing with respect to Novartis drugs generally.

XIII. Novartis Caused Thousands of False Claims to be Submitted to and Paid For by Federal Health Care Programs

175. Novartis caused many thousands of prescriptions to be written as a result of payments and/or other remuneration made in connection with speaker programs that were kickbacks to doctors. Novartis paid tens of thousands of doctors kickbacks in the form of honoraria and/or other remuneration in conjunction with speaker programs on Lotrel, Valturna, Starlix and other CV division drugs during the period from January 2002 through November 2011. On average each of these doctors wrote many thousands of dollars' worth of prescriptions for these drugs that were paid for by federal health care programs.

176. Each of the following doctors, who are discussed above in paragraphs 151 through 158, wrote prescriptions that were induced by honoraria and/or other remuneration:

- **Dr. S.D.2.** During the above-referenced period when Dr. S.D.2 received honoraria payments in connection with Lotrel — June 2005 through July 2007 — he wrote \$85,949.82 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$156.79 worth of prescriptions for Lotrel that were paid for by TRICARE. Similarly, during the above-referenced period when Dr. S.D.2 received honoraria in connection with Valturna — October 2009 through November 2011 — he wrote \$18,855.77 worth of prescriptions for Valturna that were paid for by a Part D Medicare Plan. In addition, from June 2005 through July 2007 and October 2009 through November 2011, Dr. S.D.2 wrote prescriptions for Diovan HCT, Tekturna HCT, Tekamlo, and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan. Attached as Exhibit A is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. B.D.** During the above-referenced period when Dr. B.D. received honoraria payments in connection with Lotrel — May 2003 through June 2007 — he wrote \$13,925.45 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$1,179.19 worth of prescriptions for Lotrel that were paid for by TRICARE. Attached as Exhibit B is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. B.A.** During the above-referenced period when Dr. B.A. received honoraria payments in connection with Lotrel — March 2006 through April 2007 — he wrote \$12,215.88 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$2,560.55 worth of prescriptions for Lotrel to patients in New York State that were paid for by Medicaid. Similarly, during the period when Dr.

B.A. received honoraria in connection with Valtuna — October 2009 through September 2011 (\$10,000 for conducting four speaker programs and \$1,250 for attending one training event) — he wrote \$5,274.61 worth of prescriptions for Valtuna that were paid for by a Part D Medicare Plan and \$5,998.20 worth of prescriptions for Valtuna to patients in New York State that were paid for by Medicaid. In addition, from March 2006 through April 2007 and October 2009 through September 2011, Dr. B.A. wrote prescriptions for Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan and Medicaid. Attached as Exhibit C is a spreadsheet with additional information regarding the above prescriptions.

- **Dr. L.M.** During the above-referenced period when Dr. L.M. received honoraria payments in connection with Lotrel — June 2006 through June 2007 — he wrote \$15,373.88 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$232.13 worth of prescriptions for Lotrel that were paid for by TRICARE. Similarly, during the above-referenced period when Dr. L.M. received honoraria in connection with Valtuna — October 2009 through November 2010 — he wrote \$917.30 worth of prescriptions for Valtuna that were paid for by a Part D Medicare Plan. In addition, from June 2006 through June 2007 and October 2009 through November 2010, Dr. L.M. wrote prescriptions for Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan and TRICARE. Attached as Exhibit D is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. S.M.2.** During the above-referenced period when Dr. S.M.2 received honoraria payments in connection with Lotrel — June 2005 through July 2007 — he wrote \$5,425.23 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan. Attached as Exhibit E is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. R.D.** During the above-referenced period when Dr. R.D. received honoraria payments in connection with Lotrel — June 2005 through May 2007 — he wrote \$10,595.65 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan. Attached as Exhibit F is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. D.S.2.** During the above-referenced period when Dr. D.S.2 received honoraria payments in connection with Lotrel — February 2006 through June 2007 — he wrote \$3,417.10 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$739.50 worth of prescriptions for Lotrel that were paid for by TRICARE. Attached as Exhibit G is a spreadsheet with additional information regarding the above prescriptions.

- **Dr. S.Z.** During the above-referenced period when Dr. S.Z. received honoraria payments in connection with Lotrel — June 2003 through May 2007 — he wrote \$5,357.54 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$3,602.12 worth of prescriptions for Lotrel that were paid for by TRICARE. Similarly, during the period when Dr. S.Z. received honoraria in connection with Valtorna — October 2009 through September 2011 (\$12,000 for conducting eight speaker programs and \$1,250 for attending one training event) — he wrote \$1,633.83 worth of prescriptions for Valtorna that were paid for by a Part D Medicare Plan. In addition, from June 2003 through May 2007 and October 2009 through September 2011, Dr. S.Z. wrote prescriptions for Diovan, Diovan HCT, Tekturna HCT, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan and TRICARE. Attached as Exhibit H is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. S.M.1.** During the above-referenced period when Dr. S.M.1 received honoraria payments in connection with Valtorna — February 2010 through October 2011 — she wrote \$8,099 worth of prescriptions for Valtorna that were paid for by a Part D Medicare Plan and \$10,107.39 worth of prescriptions for Valtorna to patients in New York State that were paid for by Medicaid. Similarly, during the period when Dr. S.M.1 received honoraria in connection with Lotrel — June 2005 through April 2007 (\$3,500 for conducting four speaker programs and \$2,500 for attending two training events) — she wrote \$14,337.07 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$23,417.03 worth of prescriptions for Lotrel to patients in New York State that were paid for by Medicaid. In addition, from June 2005 through April 2007 and February 2010 through October 2011, Dr. S.M.1 wrote prescriptions for Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan and Medicaid. Attached as Exhibit I is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. N.D.** During the above-referenced period when Dr. N.D. received honoraria payments in connection with Starlix — February 2004 through August 2006 — he wrote \$6,234.97 worth of prescriptions for Starlix that were paid for by a Part D Medicare Plan and \$14,314.72 worth of prescriptions for Starlix to patients in New Jersey that were paid for by Medicaid. Similarly, during the period when Dr. N.D. received honoraria in connection with Lotrel and Valtorna — June 2005 through August 2007 (\$15,350 for conducting 11 Lotrel speaker programs and \$6,500 for attending four Lotrel training events) and October 2009 through November 2011 (\$9,000 for conducting nine Valtorna speaker programs and \$1,250 for attending one Valtorna training event) — he wrote \$13,845.82 worth of prescriptions for Lotrel and \$1,472.63 for Valtorna that were paid for by a Part D Medicare Plan, and \$6,664.09 worth of prescriptions for Lotrel and \$949.92 for Valtorna to patients in New Jersey that were paid for by Medicaid. In addition, from February 2004 through August 2007 and October 2009 through November 2011, Dr. N.D. wrote prescriptions for Diovan, Diovan HCT, Tekturna, Exforge

and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan and Medicaid. Attached as Exhibit J is a spreadsheet with additional information regarding above prescriptions.

- **Dr. T.M.** During the above-referenced period when Dr. T.M. received honoraria payments in connection with Lotrel — February 2003 through June 2007 — he wrote \$1,216.55 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan. Similarly, during the period when Dr. T.M. received honoraria in connection with Valtorna and Starlix — October 2009 through November 2010 (\$7,000 for conducting seven Valtorna speaker programs and \$1,250 for attending one Valtorna training event) and February 2003 through August 2006 (\$3,400 for conducting four Starlix speaker programs) — he wrote \$197.20 worth of prescriptions for Valtorna and \$2,184.04 for Starlix that were paid for by a Part D Medicare Plan. In addition, from February 2003 through June 2007 and October 2009 through November 2010, Dr. T.M. wrote prescriptions for Diovan, Diovan HCT, Tektorna, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan. Attached as Exhibit K is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. S.D.1.** During the above-referenced period when Dr. S.D.1 received honoraria payments in connection with Lotrel — July 2006 through May 2007 — he wrote \$8,715.95 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan. Similarly, during the period when Dr. S.D.1 received honoraria in connection with Valtorna — October 2009 through March 2011 (\$6,000 for conducting six speaker programs and \$1,250 for attending one training event) — he wrote \$2,239.97 worth of prescriptions for Valtorna that were paid for by a Part D Medicare Plan and \$905.84 worth of prescriptions for Valtorna that were paid for by TRICARE. In addition, from July 2006 through May 2007 and October 2009 through March 2011, Dr. S.D.1 wrote prescriptions for Diovan, Diovan HCT, Tektorna, Tektorna HCT, Tekamlo, and Exforge. These prescriptions were paid for by a Part D Medicare Plan and TRICARE. Attached as Exhibit L is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. D.S.1.** During the above-referenced period when Dr. D.S.1 received honoraria payments in connection with Lotrel — July 2006 through July 2007 — he wrote \$27,587.66 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$10,972.24 worth of prescriptions for Lotrel to patients in New Jersey that were paid for by Medicaid. Similarly, during the period when Dr. D.S.1 received honoraria in connection with Valtorna and Starlix — October 2009 through June 2011 (\$11,250 for conducting eight Valtorna speaker programs and \$1,250 for attending one Valtorna training event) and October 2002 through July 2006 (\$4,750 for conducting seven Starlix speaker programs) — he wrote \$7,268.70 worth of prescriptions for Valtorna and \$5,803.39 for Starlix that were paid for by a Part D Medicare Plan, and \$4,313.46 worth of prescriptions for Valtorna and \$36,337.67 for Starlix to patients in New Jersey that were paid for

by Medicaid. In addition, from October 2002 through July 2007 and October 2009 through June 2011, Dr. D.S.1 wrote prescriptions for Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan. Attached as Exhibit M is a spreadsheet with additional information regarding the above prescriptions.

- **Dr. C.V.S.** During the period when Dr. C.V.S. received honoraria payments in connection with Lotrel — October 2002 through May 2007 (\$25,750 for conducting 31 speaker programs and \$3,000 for attending two training events) — he wrote \$21,682.12 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$3,425.14 worth of prescriptions for Lotrel that were paid for by TRICARE. Attached as Exhibit N is a spreadsheet with additional information regarding the above prescriptions.
- **Dr. S.G.** During the period when Dr. S.G. received honoraria payments in connection with Lotrel — July 2003 through July 2007 (\$13,500 for conducting 15 speaker programs and \$6,500 for attending four training events) — he wrote \$6,660.61 worth of prescriptions for Lotrel that were paid for by a Part D Medicare Plan and \$3,404.01 worth of prescriptions for Lotrel that were paid for by TRICARE. Attached as Exhibit O is a spreadsheet with additional information regarding the above prescriptions.

177. In addition, during the period that they received honoraria payments from Novartis, some doctors wrote prescriptions for at least some of the above-referenced drugs that were paid for by the VA. For example, one doctor from Des Moines, Iowa, wrote three prescriptions for Diovan that were paid for by the VA between March 2010 and May 2010. This doctor received \$19,250 in honoraria in connection with Valturna between October 2009 and April 2011, including \$3,000 for speaker programs in March 2010 and \$4,500 for speaker programs in April 2010. Another doctor from New Braunfels, Texas, wrote five prescriptions for Starlix and Diovan HCT that were paid for by the VA between June 2005 and January 2007. This doctor received \$14,500 in honoraria from Novartis during that time period, including \$7,500 for speaking on Starlix.

178. Novartis is liable to the federal government for damages based on the payment of the above claims and all other claims submitted to federal health care programs for prescriptions written by these physicians for the relevant Novartis drugs beginning from the time they began

receiving honoraria payments or other remuneration and running through at least 2011, because the claims were the result of prescriptions induced by honoraria or other remuneration.

179. Compliance with the Anti-Kickback Statute is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements, and contracts.

180. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to physicians as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for prescriptions written by the doctors that took the kickbacks from Novartis.

181. Claims for Novartis's prescriptions drugs arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS. 42 U.S.C. § 1320a-7b(b).

182. By providing remuneration to physicians and other health care professionals, Novartis intended to induce those physicians to prescribe certain of Novartis's drugs. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to federal health care programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by federal health care programs.

FIRST COUNT

**Violations of the False Claims Act: Presenting False Claims for Payment
(31 U.S.C. § 3729(a) (1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))**

183. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

184. The United States seeks relief against defendant under Section 3729(a)(1) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

185. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), false and fraudulent claims for payment based on these prescriptions were made to federal health care programs. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

186. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND COUNT

**Violations of the False Claims Act: Use of False Statements
(31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))**

187. The United States incorporates by reference paragraphs 1 through 186 as if fully set forth herein.

188. The United States seeks relief against defendant under the False Claims Act, 31 U.S.C. § 3729(a)(2)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

189. As a result of Novartis's kickbacks to induce doctors to prescribe Novartis drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Novartis knowingly caused doctors to make false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs. Those false records or statements by physicians in turn caused the certifications and attestations signed by pharmacies, PBMs and Part D sponsors that certified compliance with the AKS to be false.

190. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

THIRD COUNT

Unjust Enrichment

191. The United States incorporates by reference each of paragraphs 1 through 190 as if fully set forth in this paragraph.

192. The United States paid claims submitted to federal health care programs in connection with Novartis drugs based on false statements submitted to federal health care programs as a result of Novartis's violations of applicable federal and state laws and regulations, including the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The circumstances of Novartis's receipt of payments based on the prescriptions written by doctors who received kickbacks are such that, in equity and good conscience, Novartis should not retain those payments, the amount of which is to be determined at trial.

WHEREFORE, the United States respectfully requests judgment against Novartis as follows:

a. On Counts One and Two (FCA) a judgment against Novartis for treble damages and civil penalties to the maximum amount allowed by law;

b. On Count Three (common law) a judgment for damages to the extent allowed by law.

Dated: August 26, 2013
New York, New York

Respectfully submitted,

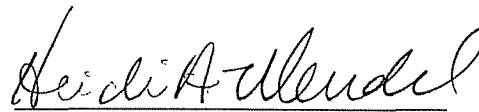
STUART DELERY
ASSISTANT ATTORNEY GENERAL

MICHAEL D. GRANSTON
JAMIE ANN YAVELBERG
NATALIE A. PRIDDY
Attorneys
U.S. Department of Justice, Civil Division

Tel: 202-616-2964
Fax: 202-514-7361

PREET BHARARA
United States Attorney for the
Southern District of New York

By:



HEIDI A. WENDEL
JEANNETTE A. VARGAS
CHRISTOPHER B. HARWOOD
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, N.Y. 10007
Tel: 212-637-2636/2678/2728
Fax: 212-637-2686